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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,800	01/17/2006	William Levine	4110-42	4537

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EXAMINER

CHEN, CATHERYNE

ART UNIT PAPER NUMBER

1655

MAIL DATE DELIVERY MODE

11/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,800

Applicant(s)

LEVINE ET AL.

Examiner

Catheryne Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Aug. 29, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendments filed on Jan. 2, 2007 has been received and entered.

Currently, Claims 1-3, 5-7 are pending. Claims 1-3, 5-7 are examined on the merits.

The declaration of affidavit of inventorship filed Aug. 9, 2007 has been considered.

Election/Restrictions

Applicant's election without traverse of *Sambucus nigra*, *Centella asiatica*, *Enchinacea purpurea* in the reply filed on Dec. 15, 2006 is acknowledged. Claim 4 is not withdrawn because it recites the elected species.

Response to Amendment

The declaration under 37 CFR 1.132 filed Aug. 9, 2007 is sufficient to overcome the rejection of Claims 1-3 based upon Domb et al. (US 2003/0003140 A1) and Claims 1-3, 5-7 based upon Domb et al. (US 2003/0003140 A1) as applied to claims 1-4 above, and further in view of Rork et al. (US 5543154) and Humber et al (US 5780046).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tyrrell et al. (US 2002/0136755 A1), Bliah (US 4742046), Rork et al. (US 5543154) and Humber et al (US 5780046).

Tyrrell et al. teaches a composition for skin contact comprising about 0.1 to about 40% by wight of viscosity enhancers of PVP/decane copolymer, PVP/eicosense, PVP/hexadecane copolymer (paragraph 0023), about 0.1 to about 10% by weight oof one or more extracted botanical actives of Echinacea purpurea, Centella asiatica (paragraph 0025). Compositions maintain their integrity and stability in a solid state for transfer to skin, including adhesion of the composition to the skin (paragraph 0037). However it does not teach the other ingredients.

Bliah teaches lectins obtained from Sambucus nigra (column 1, line 15), in form of a pharmaceutical composition to said animals or man in pharmaceutically acceptable carriers (column 4, lines 15-16, 19-20), for topical application are formulated in a semi-solid material such as oleaginous ointment bases (column 7, lines 43-45).

Rork et al. teaches an acrylic acid called CARBOPOL 974P (column 4, lines 34-37), excipients such as lactose, polyvinylpyrrolidone to make tablets, active agents from

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about 0.01% to about 75% of the core weight (column 7, lines 26, 28-29, 32, 36-37), polymeric coating is applied to and adheres to the entire surface of the core (column 9, lines 8-9), povidone (K29-32 (column 10 line 59), tablets were rolled to prevent sticking (column 11, lines 5-6).

Humber et al. teaches formulation for tablet with hydroxypropyl cellulose (column 9, line 1).

An acceptable form of administering a topical pharmaceutical compound is to use drugs applied on an adhesive on the skin. Thus, an artisan of ordinary skill would reasonably expect that the topical ingredients of *Sambucus nigra*, *Centella asiatica*, and *Echinacea purpurea* could be used as the types of medical adhesives taught by the references. This reasonable expectation of success would motivate the artisan to use *Sambucus nigra*, *Centella asiatica*, and *Echinacea purpurea* in the reference composition. Thus, using *Sambucus nigra*, *Centella asiatica*, and *Echinacea purpurea* is considered an obvious modification of the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an

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artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Catheryne Chen
Patent Examiner
Art Unit 1655

/Susan Hoffman/
Primary Examiner, Art Unit 1655
October 24, 2007